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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,463	02/17/2004	Steven D. Goedeke	P-11547.00	1783

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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/781,463

Applicant(s)

GOEDEKE, STEVEN D.

Examiner

Christopher A. Flory

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-15 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claims 9-15 stand rejected** under 35 U.S.C. 102(e) as being anticipated by Amely-Velez et al. (US Patent 6,535,765 hereinafter Velez'765).

Regarding claims 9 and 10, Velez'765 discloses a method of confirming the presence or absence of programmable memory, loading an operation instruction from the programmable memory if it is present, and loading an operation instruction from a non-programmable memory if it is not (column 8, lines 6-25).

Regarding claims 11-15, Velez'765 discloses an implantable cardioverter/defibrillator including a physiologic sensor (column 6, lines 20-62; Figure 1) comprising a processor (microcontroller 60); a non-programmable, non-volatile memory circuit and module (ABSTRACT; column 2, lines 52-55); a connector element (data/address bus 96) configured to couple to a programmable non-volatile memory module (column 2, lines 42-55; column 4, lines 46-56); and a detector circuit configured to detect a presence or absence of the programmable non-volatile memory (column 7,

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lines 6-14; column 8, lines 6-25); wherein the programmable non-volatile memory comprises flash memory or EEPROM (column 9, lines 19-24).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Velez'765.

Regarding claims 1-3, Velez'765 discloses a method comprising providing a first model of an implantable medical device (IMD) including a non-programmable non-volatile memory and a programmable non-volatile memory (Fig. 3, step 200; column 2, lines 42-55; column 4, lines 46-56) and providing a subsequent model derived from the first, wherein the subsequent model excludes the programmable non-volatile memory (Fig. 3, step 204; column 1, lines 62-67; column 3, lines 2-3);

It is noted that the limitation of excluding or not including the programmable non-volatile memory does not distinguish over the prior art. The claim language "does not include" does not require the physical removal of the RAM unit, but merely a state in which the RAM is not used to deliver operating instructions to the device. Therefore to "not include" the programmable memory can be achieved by not considering any instructions from the programmable sectors—effectively the microprocessor does not

read from RAM in the subsequent model, as is the case in Velez'765 (column 7, lines 32-63). It would have been within the skill of the art to substitute the software "blanking" of the RAM memory unit with a physical removal of the programmable non-volatile memory as claimed in the current application, since they are alternate equivalents and it has generally been held to be within the skill level of the art to substitute alternate equivalent expedients. Furthermore, omission of an element and its function is obvious when the function of the element is not desired (*Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975)). In this case, to not include the RAM module in the second product phase, whether by physical removal or by not using operating instructions stored within the RAM module that is still present is an obvious expedient when the RAM module is not desired.

Regarding claims 2-4, Velez'765 discloses the method as previously recited, wherein the programmable non-volatile memory comprises flash memory or EEPROM (column 9, lines 19-24) and stores operation instructions in the first model (Fig. 3, step 202) column 2, line 66 through column 3, line 5); wherein the non-programmable non-volatile memory comprises ROM (ABSTRACT; column 2, lines 52-55)

Regarding claim 7, Velez'765 discloses a detector circuit configured to detect a presence or absence of the programmable non-volatile memory (column 7, lines 6-14; column 8, lines 6-25).

Regarding claim 8, Velez'765 discloses that the non-programmable non-volatile memory in the second model stores at least one operation instruction stored in the

programmable non-volatile memory of the first model (column 7, lines 37-46; column 9, lines 34-45).

5. **Claims 5-6 stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Velez'765 in view of Admitted Prior Art (Admission).

Regarding claims 5-6, Velez'765 discloses the invention substantially as claimed except that the stabilization period between providing the first and second models comprises ninety days to one year. Admission teaches that the stabilization period for a typical implantable device is about ninety days to 3 three years (paragraph [23]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to establish a 90 day to one year stabilization period between programming the first model of the Velez'765 device and reprogramming (providing) the subsequent model.

Response to Arguments

6. The claim objections brought forth in the Office action dated 12 May 2006 have been successfully addressed by the Applicant in the submitted amendment. Therefore, these objections are withdrawn.

7. Applicant's arguments, see page 1, lines 16-17 of the Response filed 22 June 2006, with respect to the objection to claim 13 for failing to further limit independent claim 12 have been fully considered and are persuasive. The objection of claim 13 has been withdrawn.

8. Applicant's arguments filed 22 June 2006 have been fully considered but they are not persuasive. With regard to the rejection of claims 9-15 under 35 U.S.C. §102(e)

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using Velez'765, Applicant argues that Velez does not teach a device that includes the optional incorporation of a programmable memory into a functioning implantable medical device. However, this argument seems to be directed solely at claim 1 and its dependent claims, since the invention claimed in claims 9-15 does not require the optional incorporation of a programmable memory, but rather a device with the ability to detect/confirm either the presence or absence of such a memory. Velez'765 does disclose such a device as stated in the rejection cited above and for the original reasons made of record in the Office action filed 12 May 2006.

9. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that Velez'765 does not teach in the broadest reasonable interpretation a device that includes the optional incorporation of a programmable memory into a functioning implantable medical device. However, changing the claim language from "exclude" to "does not include" does not by itself necessitate the physical removal of the RAM unit from the implanted medical device to consider the RAM to not be included. Merely not reading instructions from the RAM unit, as taught in Velez'765, is still sufficient within a reasonable interpretation of the claim language to constitute "not including" the RAM unit. Even though the Velez'765 invention does physically present both RAM and ROM in both device phases, the exclusion of the RAM unit during the second phase with regard to providing operating instructions to the device is considered and exclusion of the RAM.

In light of Applicant's arguments that Velez'765 teaches that it would be undesirable to physically remove the RAM, omission of an element and its function is obvious when the function of the element is not desired (*Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975)). In this case, to not include the RAM module in the second product phase, whether by physical removal or by not using operating instructions stored within the RAM module that is still present, is an obvious expedient when the RAM module and its function are not desired.

Therefore, whether it is considered that to "not include" the RAM in the subsequent product model can only be interpreted as meaning the physical removal of the RAM from said model, or whether it may also encompass the interpretation that not including the instructions stored on the RAM in the subsequent model is sufficient, Velez'765 makes a sufficient case of obviousness to reject the claims of the instant application.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

13 September 2006


George Manuel
Primary Examiner